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Michael S. Williams

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

LIN, JAMES

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

04/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Box 11:

Applicant argues on pg. 10 that the data presented in Table 3 and in Figs. 10-11 of Igaki support the conclusion that the methods of Igaki in fact teach that only a single concentration of drug is impregnated in the polymeric material of Igaki. However, the data merely shows the amount in weight of the drug impregnated in the polymeric material. There is no connection between the amount of drug impregnated and the concentration gradient of the drug in the polymeric material.

Applicant notes on pg. 10-11 that the rejection in the Office Action has a basis that a concentration gradient of the drug in the polymeric material is inherent because Igaki teaches removing the pressure over a predetermined period of time and under controlled conditions and argues that the MPEP 2141.02 states that “[o]bviusness cannot be predicated on what is not known at the time an invention was made, even if the inherency of a certain feature is later established”. However, the recitation in MPEP 2141.02.V. does not give a clear indication of the context of which it is being used because the rejection that was reversed was on the basis that a parameter optimized was not recognized in the art to be a result-effective variable, and not on any sort of basis of inherency. Applicant is directed to MPEP 2112.II., which states that “[t]here is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference” (emphasis in original).

Applicant argues on pg. 11 that the only method provided in Igaki for controlling the release time point and quantity of an impregnated drug is via the use of layers of diodegradable polymer material and not via a concentration gradient and that these teachings of Igaki teaches away from the use of concentration gradients. Although Igaki may suggest other ways to control the release time point and quantity of an impregnated drug, the concentration gradient of the drug in the polymer material is inherent its disclosed method. The basis of inherency is not what would have been obvious to one skilled in the art, but that the method as a whole would have necessarily resulted in such an outcome. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require

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applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied upon. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

Applicant argues on pg. 11-12 that the Office Action states that a predetermined concentration gradient can be zero and argues that, based on the definitions of "gradient" and "concentration gradient", one of ordinary skill in the art would not consider a concentration gradient to be zero. However, the claims merely require "a predetermined concentration gradient" without any sort of range. A concentration gradient of zero is a predetermined concentration gradient.

Applicant argues on pg. 13 that the Office Action does not provide any evidence for the contention that "[t]here must be some control of how fast the rate of pressure changes" in the rejection over Greiner. However, Greiner teaches that the pressure is lowered in the reactor. The change in pressure must be manipulated by an operator and/or a computer and the pressure must necessarily be released at some rate. This rate of release has been interpreted to be a controlled rate.

Applicant's arguments, see pg. 13-14, filed 4/18/2008, with respect to claims 86 and 98 over Greiner have been fully considered and are persuasive. The rejection of the claims has been withdrawn. It should be noted that claim 86 is still rejected over Igaki and claims 86 and 98 are still rejected over Greiner in view of Igaki.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is (571)272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jimmy Lin/
Examiner, Art Unit 1792

/Timothy H Meeks/
Supervisory Patent Examiner, Art Unit
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